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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,216	06/13/2001	Robert E. Richard	12013/59001	4088

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WASHINGTON, DC 20005

EXAMINER
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TSOY, ELENA

ART UNIT	PAPER NUMBER
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1762

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08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/879,216	<b>Applicant(s)</b> RICHARD, ROBERT E.	
	<b>Examiner</b> Elena Tsoy	<b>Art Unit</b> 1762	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-43, 45-57 and 59-62 is/are pending in the application.
- 4a) Of the above claim(s) 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-43, 45-57, 59, 60 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/26/2007</u> . | 6) <input type="checkbox"/> Other: _____  |

### ***Response to Amendment***

Amendment filed on June 26, 2007 has been entered. Claims 44 and 58 have been cancelled. New claims 59-62 have been added. Claims 36-43, 45-57, and 59-62 are pending in the application.

### ***Election/Restrictions***

Newly submitted claim 61 is directed to a species that is independent or distinct from the invention previously claimed for the following reasons: this application contains claims directed to the following patentably distinct species of the claimed invention: the species of claim 56 is directed to the embodiment in which the first SCF is the same as the second SCF, whereas the species of new claim 61 is now directed to an alternative embodiment, in which the first SCF is different from the second SCF. Thus the species of claim 61 is independent or distinct from the invention of claim 56 as filed with an earlier amendment and previously examined. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.

Since applicant has received an action on the merits for the previously presented invention, this invention has been constructively elected by previous presentation for prosecution on the merits. Accordingly, claim 61 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Double Patenting***

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Objection to claim 44 under 37 CFR 1.75 as being a substantial duplicate of claim 43 has been withdrawn due to cancellation of the claim.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 37-39, 41-43, 46-48, 52, 54-57, 59-60, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu (US 6,203,551) in view of Sand (US 4,598,006).

Wu in view of Sand is applied here for the same reasons as set forth in paragraph 6 of the Office Action mailed on 2/28/2007.

As to claims 52 and 62, as was discussed in paragraph 6 of the Office Action mailed on 6/26/2006, Sand teaches that the swell loading process can be carried out by directing compressed CO<sub>2</sub> feed line (claimed first fluid source) to an autoclave containing a polymer article and pumping SCF to an intermediate pressure, then directing a compressed CO<sub>2</sub> feed line through a small vessel which contains impregnant so that CO<sub>2</sub> becomes laden with the impregnant (claimed second fluid source), then forcing the impregnant-laden CO<sub>2</sub> into the autoclave (See column 5, lines 11-24).

The Examiner Note: the intermediate pressure of compressed CO<sub>2</sub> would cause the polymer swell so that a pharmaceutical solution would be added to the swollen polymer, as required by Amendment of claim 52.

Regarding the collection operation of claims 59-60, Examiner notes that the cited prior art's method of swell loading a stent with a solution of a therapeutic agent will not result in

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attachment of all therapeutic agent that is present in solution. After loading, excess supercritical fluid, with therapeutic agent dissolved there, will remain. Due to the high expense of pharmaceutical products, it is Examiner's position that one of ordinary skill in the art would collect the excess solution to recover the expensive pharmaceutical agents therein for a subsequent coating operation, as required by the claims. Obviously, the recycling of the coating substance would produce significant cost savings in any coating process when an expensive therapeutic agent is being used for coating. Therefore, it would have been obvious to one having ordinary skill in the art to have collected and removed therapeutic in Wu and Sand with the expectation of providing the desired significant cost savings when an expensive therapeutic agent is being used.

5. Claims 37-39, 41-43, 46-48, 52, 54-57, 59-60, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sand in view of Wu for the reasons set forth in paragraph 7 of the Office Action mailed on 2/28/2007 and for the reasons, discussed above.

6. Claims 37-39, 41-43, 46-48, 52, 54-57, 59-60, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu, further in view of Stack et al (US 5,527,337) for the reasons set forth in paragraph 8 of the Office Action mailed on 2/28/2007 and for the reasons, discussed above.

7. Claims 40, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Mehta et al (US 6,627,246) for the reasons set forth in paragraph 9 of the Office Action mailed on 2/28/2007 and for the reasons, discussed above.

8. Claims 45, 50, 51, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu in view of Sand/Sand in view of Wu/Wu in view of Sand further in view of Stack et al/Sand in view of Wu further in view of Stack et al/, and further in view of Allen et al (US 6,495,204) for the reasons set forth in paragraph 10 of the Office Action mailed on 2/28/2007 and for the reasons, discussed above.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Hossainy et al (US 6,860,946) is provided as an evidence to substantiate the theory that it would have been obvious to one having ordinary skill in the art to have collected and removed therapeutic as required by the claims, since Hossainy et al teach, "The recycling of the coating substance can produce significant cost savings when an expensive therapeutic agent is being used" (See column 8, lines 1-5).

### ***Response to Arguments***

10. Applicants' arguments filed June 26, 2007 have been fully considered but they are not persuasive.

#### **b. The Wu Reference**

By the Examiner's own admission, Wu fails to teach a process that uses a supercritical fluid (hereinafter "SCF") as a solvent in a swell loading process comprising swelling the polymer with a swelling agent devoid of a therapeutic. See ¶ 4 of the June 26, 2006 Office Action.

#### **c. The Sand Reference**

In an attempt to cure this deficiency, the Office Action cites Sand. The Applicant respectfully submits that Sand does not disclose temporarily swelling coating with a SCF devoid of coating.

The argument is unconvincing because it is the Examiner's position that the intermediate pressure of compressed CO<sub>2</sub> would cause the polymer swell so that a pharmaceutical solution would be added to the **swollen** polymer, as required by Amendment of claim 52. The Examiner's position is maintained since Applicants didn't submit any *factual* data that SCF pumped to an intermediate pressure did not swell the coating.

#### **d. The Stack Reference**

In another attempt to cure the deficiencies of Wu, the Office Action cites Stack. The passage of Stack: " Very small pores can be created by swelling the polymer at any stage post-extrusion in a SCF such as propane and then reducing the pressure so that no *liquid* phase exists. In all cases, drug containing solutions can be forced into the pores by hydrostatic pressure with

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or without a gelling agent to control out-diffusion of the drug." See col. 12, lines 4-10. Although this passage discusses swelling a polymer with a SCF such as propane, it does not address temporarily swelling a coating with a SCF devoid of therapeutic as claimed in the present application. Rather, this cited passage of Stack addresses the permanent creation of very small pores in a polymer that will comprise a stent.

The Examiner respectfully disagrees with this argument. Even if it is agreed that Stack fails to teach that collapsing the swollen polymer, as was discussed in the paragraph of the Office action mailed on 2/28/2007, Wu teaches that after soaking stent 28 with the solution, the stent 28 is rapidly dried causing the polymer to collapse (claimed temporarily swelling), trapping a high concentration of the substance into the polymer's matrices (See column 9, lines 47-53).

Obviously, drying SCF would also collapse the polymer, as required by Amendment.

Therefore, it would be obvious to rapidly dry a swell loaded coating with the expectation of providing the desired trapping a high concentration of the substance into the polymer's matrices due to the collapse of the polymer, as taught by Wu.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is 571-272-1429. The examiner can normally be reached on Monday-Thursday, 9:00AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elena Tsoy  
Primary Examiner  
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August 6, 2007